

Imaging as a Biomarker: Standards for Change Measurements in Therapy

Breakout Area 5: Resources for Qualification of Imaging Systems:
Benchmarking of Imaging Processing and Data Integration Tools
and Related Statistical Methods

Day 2: Summary

“The Detailed Measurement Science & Standards Needs –
The What by When and by Whom”
Near, Mid-Term Issues Only

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Measurement Need for Near, Mid, Long Term

1. *Technology at Issue: **Large public datasets with data, imaging parameters and protocols in standard format***
2. *Submitter(s):* Participants of Breakout Area 5
3. *Technological Innovation at Stake:*
 - ☐ Benchmark/standardize and improve image analysis technique
 - ☐ Infrastructure for collecting/sharing clinical trial, academic and normal clinical data
 - ☐ “Improve”/standardize truthing and annotation
 - ☐ Understanding or appropriate training and test paradigms
4. *Economic Significance of Innovation:*
 - ☐ Reduce software tool development/validate costs
 - ☐ May drive down cost of clinical trials
 - May reduce the need for controls in some trials
 - ☐ Effort/cost by centers to provide nonstandard information

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5. *Technical Barrier to the Innovation:*

- ☐ *Infrastructure for collecting/sharing clinical trial, academic and normal clinical data*
- ☐ *Need to establish/unify measures of response*
- ☐ *Truening/Annotating data*
- ☐ *Implementation to collecting necessary “raw” data*
- ☐ *Need for different data for different diseases*
- ☐ *Continuous effort to acquire data*
- ☐ *Where/how to host data?*
- ☐ *Support from patient, health insurance companies*

6. *Stage of Innovation Where Barrier Appears:*

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Measurement Need #1 for Near-Term 1-3 Years (cont'd)

7. *Measurement-Problem Part of Technical Barrier.*

- ☐ Truthing and annotation
- ☐ Need for training/test paradigms
- ☐ How to keep database relevant?
- ☐ Need for metrics
 - Can't compare results from different systems

8. *Potential Solutions to Measurement Problem:*

- ☐ *Development of generic kernel to represent “raw” data*
- ☐ *Development of metrics*
 - *Needs directed discussion for individual application*
- ☐ *New statistical ideas for imaging in clinical trials*
- ☐ *Training of readers with tools?*

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Measurement Need #1 for Near-Term 1-3 Years (cont'd)

9. *Potential Providers of Solutions:*

- ☐ *ASA, FDA, NIST, NIH, NEMA, ICL, Clinical centers, Research community, PhRMA*

10. *What is the role for Government, if Any?:*

- ☐ *Develop correct task-specific validation methods*
 - *Promote consensus process for these methods*
 - *Government recognition of any standards*
 - *Not lead role usually*
- ☐ *Enhancing data sharing*
- ☐ *Maintaining data*

11. *If There is a Government Role, Why Industry Says It Can't/Won't Pay for That Part of Solution:*

- ☐ *Industry supplies data*
- ☐ *Government houses data*